

REMARKS

The Office Communication states:

The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter. Note that the applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). (Office Communication, p. 1).

The Examiner indicates that Applicant's amendment to the claims, filed as a submission with the RCE on June 16, 2003, results in a change in the method steps such that pending claims 1, 4, and 5 are now directed to a different invention. The Examiner states that the previous method steps required "determining the presence of apoE4 alleles and then the absence of [apoE4] alleles indicates a result," whereas the method of present claim 1 now requires "determining apoE4 alleles where in the absence of one of the alleles indicates a result" (Office Action, p. 1). The Examiner further states that "it is not clear how one will know if an allele is not present, because it would not be present in the determination of apoE4 alleles" (Office Action, p. 1).

In response, Applicant points out that independent claims 1, 4, and 5, as presently amended, recite determining the "apoE allele load" of the subject or patient, in which the absence of apoE4 gene allele indicates a result. The method steps of present claims 1, 4, and 5, like that of previously examined claims 1, 4, and 5, involve a determination of the apoE4 status of the subject or patient (i.e., a determination of which apoE alleles a subject or patient has) so that the absence of the apoE4 gene allele can be established. Because present claims 1, 4, and 5 recite that the absence of the apoE4 gene allele indicates a result, present claims 1, 4, and 5 are not separate and distinct from the method steps of previously examined claims 1, 4, and 5.

Furthermore, by reciting that the method involves "determining the apoE allele load" of a subject or patient rather than "determining the presence of apoE4 gene alleles," the present

amendment of claims 1, 4, and 5 serves to clarify the method by indicating that the actor would first determine which apoE alleles are present in a subject or patient, thereby allowing the actor to subsequently determine whether apoE4 gene alleles are absent. Because a subject or patient has only two apoE gene alleles selected from apoE2, apoE3, and apoE4 or combinations thereof, the actor need only determine the presence of an apoE2 gene allele pair, an apoE3 gene allele pair, or an apoE2/apoE3 gene allele pair (i.e., the absence of apoE4 gene alleles) to establish the result recited in present claims 1, 4, or 5. Alternatively, the actor can look for the presence of apoE4 gene alleles in a patient or subject. The failure to identify apoE4 gene alleles in the patient or subject also establishes the result recited in present claims 1, 4, or 5.

By providing a positive detection step that would establish the absence of an apoE4 allele, the present amendment to claims 1, 4, and 5 clearly addresses the Examiner's concern regarding how one will know if an apoE4 allele is not present. In addition, Applicant has added new claim 9, which recites that determining the apoE allele load is by genotyping. Support for new claim 9 can be found in the specification on, for example, page 28, lines 9-17.

Because the subject matter recited in present claims 1-5 and 8-9 does not differ from the subject matter recited in previously examined claims 1-5 and 8 (i.e., both require a determination of whether a subject or patient lacks apoE4 gene alleles, in which the determination leads to the result recited in claims 1, 4, or 5), Applicant respectfully submits that the invention of present claims 1-5 and 8-9 is not separate and distinct from the invention of previously examined claims 1-5 and 8. Accordingly, the Request for Continued Examination filed on June 16, 2003 is a request to provide continued examination of an application with claims directed to a previously elected invention.

With respect to the rejection of claims 1-5 and 8 for obviousness-type double patenting over claims 1-4 of U.S. Patent No. 5,935,781 ('781 patent), Applicant will submit a terminal disclaimer in compliance with 37 C.F.R. 1.321(c) once notice of otherwise allowable subject matter is received.

CONCLUSION

Applicant respectfully submits that the present amendment is a *bona fide* attempt to fully respond to the Examiner's comments provided in the Advisory Action of January 23, 2003, and that the application is now in condition for continued examination, which action is respectfully requested.

Enclosed is a petition to extend the period for replying for five months, to and including April 7, 2004.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



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for _____

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